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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,434	05/15/2001	Uwe Trinks	103057-157-NP	9018

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EXAMINER
EHICHIOYA, FRED I

ART UNIT	PAPER NUMBER
2172	7

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/855,434	TRINKS ET AL.	
	Examiner	Art Unit	
	Fred I. Ehichioya	2172	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 - 33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 - 33 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The application has been examined.

2. Claims 1 – 33 are pending in this office action.

Claim Rejections - 35 USC § 112

3. Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 5, 8, 10, 11, 12, 13, 23, 24, 25 are rejected under 35 U.S.C 102(e) as been anticipated by U.S. Patent 6,128,620 issues to Patricia L. Pissanos et al (hereinafter "Pissanos").

Regarding claim 1, Pissanos teaches a method of dynamically managing and improving the reliability, accuracy and quality of collected information comprising;

presenting a user with a hierarchically structured set of predefined terms (see Fig.7; column 2, lines 64 – 67; column 3, lines 1 – 3; column 4, lines 27 – 42 and lines 56 – 59);

receiving reported information from a user corresponding to at least one of said predefined terms (see column 3, lines 5 – 8);

structuring, categorizing and characterizing said reported information (see column 5, lines 50 – 58);

dynamically converting said reported information into a standardized output (see column 5, lines 58 – 65 and column 6, lines 12 – 17); and

storing said standardized output (see column 17, lines 15 – 25)

Regarding claim 2, Pissanos teaches hierarchically structured set of predefined terms comprises medical symptoms (see column 5, lines 58 – 60).

Regarding claim 4, Pissanos teaches hierarchically structured set of predefined terms comprises industry standard information (see column 11, lines 24 – 41).

Regarding claim 5, Pissanos teaches hierarchically structured set of predefined terms comprises performance measurement information (see column 9, lines 29 – 38 and column 10, lines 28 – 33).

Regarding claim 8, Pissanos teaches reported information comprises medical information (see column 2, lines 61 – 64).

Regarding claim 10, Pissanos teaches reported information comprises industry standard information (see column 11, lines 24 – 41).

Regarding claim 11, Pissanos teaches reported information comprises performance measurement information (see column 9, lines 29 – 38 and column 10, lines 28 – 33).

Regarding claim 12, Pissanos teaches structuring, categorizing and characterizing said reported information includes (see column 5, lines 50 – 58)

Regarding claim 13, Pissanos teaches dynamically converting said reported information into a structured and standardized output includes (see column 5, lines 58 – 65 and column 6, lines 12 – 17)

Regarding claim 23, Pissanos teaches a system for dynamically managing and improving the reliability, accuracy and quality of collected information comprising;

a computer having an interface for displaying information wherein said computer includes a central computer processing device, which includes (see column 14, lines 44 – 46 and column 16, lines 11 – 24))

a storage device for storing a hierarchically structured set of predefined terms and for saving standardized output (see column 3, lines 31 – 38 and column 17, lines 15 – 25),

a processor, programmed to (see column 7, lines 47 – 55)

present the user with a hierarchically structured set of predefined terms; receive reported information from a user corresponding to at least one of said predefined terms (see Fig.7; column 2, lines 64 – 67; column 3, lines 1 – 3; column 4, lines 27 – 42 and lines 56 – 59);

structure, categorize and characterize said reported information (see column 5, lines 50 – 58);

dynamically convert said reported information into a standardized output (see column 5, lines 58 – 65 and column 6, lines 12 – 17); and

save said standardized output (see column 17, lines 15 – 25).

Regarding claim 24, Pissanos teaches a method of accepting, managing and storing data for improving the reliability, accuracy and quality of collected information comprising:

a. establishing in a database at least one data structure containing a plurality of predefined terms (see column 2, lines 6 – 17 and column 7, lines 62 – 67);

b. running an information gathering session (see column 13, lines 63 – 67 and column 14, lines 1 – 60);

c. prompting for termination of said information gathering session, said information gathering session comprising (see column 14, lines 60 – 62)

i. sequentially displaying data comprising said plurality of predefined terms according to a predetermined set of rules (see column 13, lines 16 – 47);

ii. selecting at least one of said plurality of predefined terms (see column 13, lines 8 – 12);

iii. constructing a temporary object having standardized information in response to step ii (see column 14, 47 – 54);

iv. iteratively repeating above steps i - iii, until the running of said information gathering session is terminated (see column 17, lines 4 – 8);

d. parsing said information associated with said temporary object to said database (see column 9, lines 45 – 47).

Regarding claim 25, Pissanos teaches step d includes:

parsing said information associated with said temporary data object to a second database (see column 9, lines 51 – 53).

Claim 33 is rejected under 35 U.S.C 102(e) as been anticipated by U.S. Patent 5,924,074 issues to Jae A. Evans

(hereinafter "Evans").

Regarding claim 33, Evans teaches a computerized method for collecting information regarding reactions to medication, comprising:

establishing a first database of medications and standardized symptoms related to the usage of said medications (see column 5, lines 13 – 21),

collecting in a second database standardized symptoms from a group of medication users (see column 5, lines 21 – 25),

grouping into predetermined categories, symptoms corresponding to medication usage (see column 6, lines 37 – 54); and

identifying occurrences of standardized symptoms (see column 6, lines 11 – 14 and column 7, lines 22 – 28).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pissanos in view of U.S. Patent 6,205,455 issued to Michael J. Umen et al (hereinafter "Umen").

Regarding claims 3 and 9, Pissanos does not explicitly teach hierarchically structured set of predefined terms or reported information comprises descriptive statistical information.

Umen teaches hierarchically structured set of predefined terms or reported information comprises descriptive statistical information (see column 6, lines 42 – 61).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine teaching of Pissanos with the teaching of Umen wherein predefined terms or reported information includes statistical data. The motivation is that these statistical data are used for clinical study. This study aids the physicians in patients' future diagnosis in other to effectively prescribe the right drugs/medication for a particular illness.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pissanos in view of U.S. Patent 6,507,829 issued to Jon Michael Richards et al (hereinafter "Richards").

Regarding claims 6 and 7, Pissanos does not explicitly teach reported information comprises spontaneous or clinical Adverse Event information.

Richards teaches reported information comprises spontaneous or clinical Adverse Event information (see column 1, lines 34 – 36 and column 4, lines 57 – 58).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine teaching of Pissanos with the teaching of Richards

wherein any symptom of a disease or malady, or degradation in the health of a patient participating in a clinical trial is termed and adverse event. The motivation is that these clinical trials are used to validate the efficacy and safety of new drugs.

Claims 14, 15, 16, 19, 20, 21, 22, 26, 27, 28, 29, 30, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pissanos in view of Evans.

Regarding claim 14, Pissanos does not explicitly teach presenting the user with a hierarchical structured set of predefined terms is performed on a computer network.

Evans teaches presenting the user with a hierarchical structured set of predefined terms is performed on a computer network (see Figs.5, 8, 9, 10, 13 and 24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine teaching of Pissanos with the teaching of Evans wherein Figs.5, 8, 9, 10 and 13 display a hierarchical structure of predefined terms. Fig.24 is a configuration of the network of the system. The motivation is that the network supports different health systems within the network. This enables the sharing of information of patients among providers.

Regarding claim 15, Evan teaches presenting the user with a hierarchical structured set of predefined terms is performed on a computer network using a graphical interface (see Figs.8, 13 and 24; column 5, lines 56 – 57 and column 11, lines 31 – 34).

Regarding claim 16, Evans teaches graphical interface incorporates a graphical depiction of a system for selecting at least one category of said predefined terms (see column 6, lines 40 – 47 and lines 64 – 67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine teaching of Pissanos with the teaching of Evans wherein the graphical user interface captures patient information. The motivation is the GUI display the information in a tabbed layout or hierarchical format. It makes the locating patient information easier.

Regarding claim 19, Evans teaches said system is a mechanical system (see column 12, lines 47 – 50).

Regarding claim 20, Evans teaches said system is an electrical system (see column 2, lines 24 – 27).

Regarding claim 21, Evans teaches said system is an electro/mechanical system (see column 7, lines 14 – 17).

Regarding claim 22, Evans teaches said system is a hybrid system (see column 12, lines 43 – 47).

Regarding claim 26, Pissanos does not explicitly teach the temporary data object is a web page.

Evans teaches the temporary data object is a web page (see column 12, lines 58 – 59).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine teaching of Pissanos with the teaching of Evans wherein the data object is a web page. The motivation is that the web page makes sharing of information among the provider instantaneous.

Regarding claim 27, Evans teaches the temporary data object is a dynamic XML page (see Fig.14).

Regarding claim 28, Evans teaches the step of running an information gathering session occurs on a computer network (see Fig.24 and column 12, lines 55 – 67).

Regarding claim 29, Evans teaches the computer network is a LAN (see column 12, lines 55 – 67).

Regarding claim 30, Evans teaches the computer network is a WAN (see column 12, lines 55 – 67).

Regarding claim 31, Evans teaches the computer network is the internet (see column 12, lines 55 – 67).

Regarding claim 32, Evans teaches the object is a mark up language document (see Fig.14 step 223).

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pissanos in view of Evans and further in view of Umen.

Regarding claim 17, Pissanos or Evans does not explicitly teach said system is a human body.

Umen teaches said system is a human body (see column 1, lines 32 – 35 and lines 54 – 55).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine teaching of Pissanos and Evans with the teaching of Umen wherein drugs are defined as articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human. The motivation is that drugs when properly administered can eradicate diseases that may affect the structure and functions of human beings.

Regarding claim 18, Evans teaches said system is an animal body (see column 1, lines 40 – 44).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fred I. Ehichioya whose telephone number is 703-305-8039. The examiner can normally be reached on M - F 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kim Y. Vu can be reached on 703-305-4393. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7239 for regular communications and 703-746-7238 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-303-3900.

Fred Ehichioya
June 29, 2003

SHAHID AL ALAM
PATENT EXAMINER